ages. The court expressly declined to find that EMS had engaged in misconduct or copying. *Electro* I, slip op. at 72–73, 79–80 n. 24. *See Read*, 970 F.2d at 826–27, 23 USPQ2d at 1435–36 (listing factors to be considered in determining whether to award increased damages). These factors, in addition to those discussed above with respect to willfulness, compel the conclusion that the award of increased damages was an abuse of discretion. *See Kloster*, 793 F.2d at 1580, 230 USPQ at 91 ("[i]f infringement [is] ... innocent, increased damages are not awardable for infringement."). Likewise, the award of attorney fees, based on an erroneous finding of willfulness, cannot stand. *See Studiengesellschaft*, 862 F.2d at 1579, 9 USPQ2d at 1287 (where judge rejected master's willfulness finding, it was proper to reverse the award of increased damages and attorney fees).

CONCLUSION

That part of the judgment holding U.S. Patents 3,882,638, 3,972,123, and 4,412,402 infringed and not invalid is affirmed. That part of the judgment awarding increased damages and attorney fees is reversed because the court's finding of willful infringement was clearly erroneous.

COSTS

Each party shall bear its own costs.

AFFIRMED-IN-PART and REVERSED-IN-PART.

F. Brantley SCOTT and John H. Burton, Appellants,

v.

Roy P. FINNEY, Appellee.

No. 94-1090.

United States Court of Appeals, Federal Circuit.

Sept. 14, 1994.

In interference proceeding involving self-contained penile implant invention, the Board of Patent Appeals and Interferences, interference No. 102,429, awarded priority to senior party on grounds that junior party failed to show reduction to practice before senior party's date of invention. Junior party appealed. The Court of Appeals, Rader, Circuit Judge, held that junior party sufficiently demonstrated reduction to practice through videotape of insertion of prototype into penis of anesthetized patient, which showed surgeon manipulating implanted device several times to successfully simulate erection.

Reversed and remanded.

1. Patents ⇐314(5), 324.5

Issue of reduction to practice of invention is question of law which Court of Appeals reviews de novo.

2. Patents ⇐113(1)

Court of Appeals reviews Board of Patent Appeals and Interference's factual findings under clearly erroneous standard.

3. Patents ⇐90(5)

To show prior invention, junior party must show reduction to practice of invention before senior party, or, if junior party reduced to practice later, conception before senior party followed by reasonable diligence in reducing it to practice; to show reduction to practice, junior party must demonstrate that invention is suitable for its intended purpose.

F. Brantley SCOTT and John H. Burton, Appellants,

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4. Patents ⇐90(5)

When testing is necessary to show proof of actual reduction to practice of invention, embodiment relied upon as evidence of priority must actually work for its intended purpose.

5. Patents ⇐90(5)

In cases requiring testing in order to show reduction to practice of invention, testing requirement depends on particular facts of each case, with court guided by commonsense approach in weighing sufficiency of testing.

6. Patents ⇐90(5)

Reduction to practice of invention does not require that invention, when tested, be in commercially satisfactory stage of development; testing need not show utility beyond a possibility of failure, but only utility beyond probability of failure.

7. Patents ⇐324.55(1)

In interference proceeding, when reviewing sufficiency of evidence of reduction to practice, Court of Appeals applies reasonableness standard.

8. Patents ⇐90(5)

Character of testing necessary to show reduction to practice varies with character of invention and problem it solves.

9. Patents ⇐106(3)

In interference proceeding involving self-contained penile implant unit permitting simulation of erection, junior party sufficiently demonstrated reduction to practice through videotape of insertion of prototype into penis of anesthetized patient, which showed surgeon manipulating implanted device several times to successfully simulate erection; showing of reduction to practice did not require human testing in actual use circumstances during intercourse.

Rudolph E. Hutz, Connolly, Bove, Lodge & Hutz, Wilmington, DE, argued, for appellants. With him on the brief was Harold Pezzner.

Thad F. Kryshak, Quarles & Brady, Milwaukee, WI, argued, for appellee. With him on the brief was Thomas W. Ehrmann.

Before LOURIE, RADER, and SCHALL, Circuit Judges.

RADER, Circuit Judge.

The Board of Patent Appeals and Interferences awarded priority in Interference No. 102,429 to the senior party, Dr. Roy P. Finney. The Board held that the junior party, Dr. F. Brantley Scott and John H. Burton, did not show a reduction to practice before Dr. Finney's date of invention. Because the Board imposed an overly strict requirement for testing to show reduction to practice, this court reverses and remands.

BACKGROUND

This interference involves Dr. Finney's United States Patent No. 4,791,917, which was accorded the benefit of its May 15, 1980 parent application, and the Scott and Burton application, Serial No. 07/241,826, which was accorded the benefit of its parent application Serial No. 06/264,202, filed May 15, 1981. Although the Scott and Burton application claims a joint invention of both applicants, Dr. Scott is the sole inventor of the subject matter in interference No. 102,429.

The invention is a penile implant for men unable to obtain or maintain an erection. The prosthetic device is a self-contained unit that permits the patient to simulate an erection. The implant contains two reservoirs connected through a valve. The invention operates by shifting the inflating liquid between the two reservoirs. When the penis is flaccid, the invention maintains inflating liquid in a reservoir at the base of the penis. A simulated erection occurs when the liquid shifts through the valve into the elongated reservoir implanted in the forward section of the penis.

Prior art devices fell into two categories: flexible rods and inflatable devices. Flexible rods had the disadvantage of making the penis permanently erect. The prior inflatable devices relied on fluid from a source and pump external to the body to inflate tubes

implanted in the penis. These devices also had several disadvantages.

The Interference Count at issue states:

> An implantable penile prosthesis for implanting completely within a patient's penis comprising at least one elongated member having a flexible distal forward section for implantation within the pendulous penis, said forward section being constructed to rigidize upon being filled with pressuring fluid; a proximal, rearward section adapted to be implanted within the root end of the penis, said rearward section containing a fluid reservoir chamber, externally operable pump means in said member for transferring fluid under pressure to said flexible distal forward section of said member for achieving an erection; and valve means positioned within said member which open when said pump is operated so that fluid is forced from said pump through said valve means into said flexible distal forward section of said chamber.

The parties to this interference had contested related subject matter in an earlier interference, No. 101,149. The count of 101,149 was a species of the generic count in this interference. Dr. Scott won that earlier interference.

In this interference, No. 102,429, Dr. Finney's application has an earlier filing date than Scott's application. Dr. Scott still has, however, an earlier conception date. Dr. Scott did not present evidence of diligence after conception of his invention. *See, e.g., Griffith v. Kanamaru*, 816 F.2d 624, 626, 2 USPQ2d 1361, 1362 (Fed.Cir.1987). Rather, Dr. Scott opted to show an actual reduction to practice before Dr. Finney's date of invention.

Before the Board, Dr. Scott's primary evidence of actual reduction to practice was a videotape. The videotape showed an operation where the surgeon inserted Dr. Scott's prototype device into the penis of an anesthetized patient. The videotape showed the surgeon manipulating the implanted device. Several times the device simulated an erection when the surgeon manipulated the valve. Several times the fluid filled the forward reservoir. Several times the surgeon returned the penis to a flaccid condition by draining the fluid back into the rear reservoir. The Board found:

> It is uncontested that the penile implant used in the in-and-out procedure did rigidify the penis by pressurization of the rear chamber and did produce an erection. After the device was actuated to form the erection, the valve mechanism was manipulated to allow the device to become flaccid....

Board opinion at 8–9.

Although not part of the count, the parties agree that the invention envisions implantation of two devices—one on either side of the penis. In the videotaped demonstration, the surgeon implanted only a single prosthesis into the patient. Although using only a single prosthesis, the videotape showed a penis with enough rigidity to produce an erection. After manipulating the implanted device through the skin to simulate having and losing an erection, the surgeon removed Dr. Scott's prototype and inserted a prior art external pump mechanism.

Dr. Scott supplied other evidence as well. He presented evidence of testing for leakage, disclosed that the fabrication material was common in implanted devices, and supplied the testimony of Dr. Drogo K. Montague, an expert in the field. Dr. Montague personally handled the device at issue and viewed the videotape. He testified that the video showed, even with only a single tube, sufficient rigidity for intercourse.

In opposition, Dr. Finney testified personally about the difficulty of determining sufficient rigidity for intercourse on the basis of insertion in an anesthetized patient. Both Drs. Finney and Montague agreed that insertion of two tubes would greatly enhance rigidity.

The Board discerned insufficient evidence to show reduction to practice. Specifically, the Board determined that Dr. Scott had not shown utility, i.e., that the device would successfully operate under actual use conditions for a reasonable length of time. Thus, the Board required "testing of an implantable medical device under actual use conditions or testing under conditions that closely simulate

actual use conditions for an appropriate period of time." Board opinion at 8.

Because Dr. Scott had not tested his device in actual intercourse or in similar conditions to intercourse for a proper period of time, the Board determined that Dr. Scott had not reduced his invention to practice. The Board awarded the count to Dr. Finney. This appeal followed.

DISCUSSION

[1, 2] The issue of reduction to practice is a question of law which this court reviews *de novo*. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376, 231 USPQ 81, 87 (Fed.Cir.1986), *cert. denied*, 480 U.S. 947, 107 S.Ct. 1606, 94 L.Ed.2d 792 (1987). This court reviews the Board's factual findings under the clearly erroneous standard. *Coleman v. Dines*, 754 F.2d 353, 356, 224 USPQ 857, 859 (Fed.Cir.1985).

[3] The Scott and Burton application was copending with that of Dr. Finney. Consequently, as the junior party in this interference, Dr. Scott had the burden to show prior invention by a preponderance of evidence. *Bosies v. Benedict*, 27 F.3d 539, 542, 30 USPQ2d 1862, 1864 (Fed.Cir.1994); *Harding v. Steingiser*, 318 F.2d 748, 748, 138 USPQ 32, 33 (CCPA 1963). To show prior invention, the junior party must show reduction to practice of the invention before the senior party, or, if the junior party reduced to practice later, conception before the senior party followed by reasonable diligence in reducing it to practice. *See Griffith*, 816 F.2d at 626.

[4] To show reduction to practice, the junior party must demonstrate that the invention is "suitable for its intended purpose." *Steinberg v. Seitz*, 517 F.2d 1359, 1363, 186 USPQ 209, 212 (CCPA 1975) (quoting *In re Dardick*, 496 F.2d 1234, 1238, 181 USPQ 834, 837 (CCPA 1974)). When testing is necessary to show proof of actual reduction to practice, the embodiment relied upon as evidence of priority must actually work for its intended purpose. *Newkirk v. Lulejian*, 825 F.2d 1581, 1582, 3 USPQ2d 1793, 1794 (Fed. Cir.1987). Because Dr. Scott relied on such testing, this court must examine the quality and quantity of testing asserted to show a reduction to practice.

Testing sufficient to show a reduction to practice has often been at issue in interference proceedings. *Newkirk*, 825 F.2d at 1582 ("proof of actual reduction to practice requires demonstration that the embodiment relied upon as evidence of priority actually worked for its intended purpose"); *see also Kimberly–Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1445, 223 USPQ 603, 607 (Fed.Cir.1984) (same); *Wiesner v. Weigert*, 666 F.2d 582, 588, 212 USPQ 721, 726 (CCPA 1981) (same). By the same token, this court has also indicated "that '[s]ome devices are so simple and their purpose and efficacy so obvious that their complete construction is sufficient to demonstrate workability.'" *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 861, 226 USPQ 402, 407 (Fed.Cir. 1985), *cert. denied*, 475 U.S. 1016, 106 S.Ct. 1197, 89 L.Ed.2d 312 (1986) (quoting *Eastern Rotorcraft Corp. v. United States*, 384 F.2d 429, 431, 155 USPQ 729, 730 (Ct.Cl.1967)). Indeed, the Supreme Court, in a case featuring evidence of testing, cited approvingly three decisions of the United States Court of Appeals for the District of Columbia which stated that simple devices need no testing to show reduction to practice. *See Corona Cord Tire Co. v. Dovan Chem. Corp.*, 276 U.S. 358, 383, 48 S.Ct. 380, 387–88, 72 L.Ed. 610 (1928) (citing *Roe v. Hanson*, 19 App. D.C. 559 (1902); *Lindemeyr v. Hoffman*, 18 App.D.C. 1 (1901); and *Mason v. Hepburn*, 13 App.D.C. 86 (1898).

[5–7] In cases requiring testing, this court's predecessor addressed many times the nature of testing necessary to show reduction to practice. Several important principles emerge from these cases. For instance, the testing requirement depends on the particular facts of each case, with the court guided by a common sense approach in weighing the sufficiency of the testing. *Gellert v. Wanberg*, 495 F.2d 779, 783, 181 USPQ 648, 652 (CCPA 1974); *Gordon v. Hubbard*, 347 F.2d 1001, 1006, 146 USPQ 303, 307 (CCPA 1965). Reduction to practice does not require "that the invention, when tested, be in a commercially satisfactory stage of development." *Dardick*, 496 F.2d at 1238;

Steinberg, 517 F.2d at 1363; *Goodrich v. Harmsen*, 442 F.2d 377, 383, 169 USPQ 553, 559 (CCPA 1971). Testing need not show utility beyond a possibility of failure, but only utility beyond a probability of failure. *Taylor v. Swingle*, 136 F.2d 914, 917, 58 USPQ 468, 471 (CCPA 1943). When reviewing the sufficiency of evidence of reduction to practice, this court applies a reasonableness standard. *Holmwood v. Sugavanam*, 948 F.2d 1236, 1238, 20 USPQ2d 1712, 1714 (Fed.Cir. 1991).

Complex inventions and problems in some cases require laboratory tests that "accurately duplicate actual working conditions in practical use." *Elmore v. Schmitt*, 278 F.2d 510, 513, 125 USPQ 653, 656 (CCPA 1960); *accord Koval v. Bodenschatz*, 463 F.2d 442, 447, 174 USPQ 451, 455 (CCPA 1972) (testing of electrical circuit breaker did not test higher voltages); *Anderson v. Scinta*, 372 F.2d 523, 527, 152 USPQ 584, 587 (CCPA 1967) (testing of windshield wiper blades did not simulate effect of wind on windshield); *but cf. Paivinen v. Sands*, 339 F.2d 217, 225–26, 144 USPQ 1, 8–9 (CCPA 1964) (oscilloscope testing of magnetic switching circuit necessarily involved high speed switching). In *Elmore*, the Court of Customs and Patent Appeals noted that the various tests on a binary counter for sophisticated radar and video equipment did not account for "the resistance and character of load, nature of pulses, including voltage, duration and amplitude, and amount of capacitance used." *Elmore*, 278 F.2d at 512. The court also noted that the tests did not "reproduce[ ] the conditions of temperature, vibration, or sustained operation which would usually be encountered in a specific use." *Id.* *Elmore* demanded closer correlation between testing conditions and actual use conditions because the presence of many variables in that precision electronics field would otherwise raise doubts about the invention's actual capacity to solve the problem.

Less complex inventions and problems do not demand such stringent testing. *See, e.g., Sachs v. Wadsworth*, 48 F.2d 928, 929, 9 USPQ 252, 254 (CCPA 1931), and cases cited in *Corona Cord*, 276 U.S. at 383, 48 S.Ct. at 387–88. In *Sellner v. Solloway*, 267 F.2d 321, 122 USPQ 16 (CCPA 1959), for example, the inventor presented his invention, an exercise chair, at a birthday party. Because "the device involved and manner in which it is intended to operate are comparatively simple," *id.* at 323, the court sustained the sufficiency of this rudimentary testing by individuals without particular skills.

[8] This court's predecessor well summarized many of these principles:

> A certain amount of "common sense" must be applied in determining the extent of testing required. Depending on its nature, the invention may be tested under actual conditions of use, or may be tested under "bench" or laboratory conditions which fully duplicate each and every condition of actual use, or in some cases, may be tested under laboratory conditions which do not duplicate all of the conditions of actual use. In instances where the invention is sufficiently simple, mere construction or synthesis of the subject matter may be sufficient to show that it will operate satisfactorily.

Gordon, 347 F.2d at 1006. This statement captures the underlying principle that governs the nature of testing necessary to show reduction to practice—the character of the testing varies with the character of the invention and the problem it solves. *See Sydeman v. Thoma*, 32 App.D.C. 362 (1909).

Another predecessor to this court summarized, "the inquiry is not what kind of test was conducted, but whether the test conducted showed that the invention would work as intended in its contemplated use." *Eastern Rotorcraft Corp. v. United States*, 384 F.2d 429, 431, 155 USPQ 729, 730 (Ct.Cl.1967). Thus, the Court of Claims focused on the workability of the invention in the context of the problem it solved. The nature and complexity of the problem necessarily influence the nature and sufficiency of the testing necessary to show a reduction to practice. In any event, the testing should demonstrate "*the soundness of the principles of operation* of the invention." *Wolter v. Belicka*, 409 F.2d 255, 263, 161 USPQ 335, 341 (CCPA 1969) (Rich, J., dissenting). The inventor need show only that the invention is "suitable" for its intended use. *Steinberg*, 517

F.2d at 1363 (quoting *Dardick*, 496 F.2d at 1238).

All cases deciding the sufficiency of testing to show reduction to practice share a common theme. In each case, the court examined the record to discern whether the testing in fact demonstrated a solution to the problem intended to be solved by the invention. *See, e.g., Farrand Optical Co. v. United States*, 325 F.2d 328, 333, 139 USPQ 249, 253 (2d Cir.1963) ("The essential inquiry here is whether the *advance in the art* represented by the invention . . . was embodied in a workable device that demonstrated that it could do what it was claimed to be capable of doing.") (emphasis added). In tests showing the invention's solution of a problem, the courts have not required commercial perfection nor absolute replication of the circumstances of the invention's ultimate use. Rather, they have instead adopted a common sense assessment. This common sense approach prescribes more scrupulous testing under circumstances approaching actual use conditions when the problem includes many uncertainties. On the other hand, when the problem to be solved does not present myriad variables, common sense similarly permits little or no testing to show the soundness of the principles of operation of the invention.

[9] In the prosthetic implants field, polyurethane materials and inflatable penile prostheses were old in the art. They were tested extensively. Only the insertion and hydraulics of a manipulable valve separating two implanted reservoirs were new. Thus, Dr. Scott had the burden to show that his novel valve and dual reservoir system would simulate an erection for sexual intercourse when manipulated through the skin. Consequently, the problem presented to Dr. Scott, when viewed from the vantage point of earlier proven aspects of penile implant technology, was relatively uncomplicated.

In the videotape presentation, Dr. Scott demonstrated sufficiently the workability of his invention to solve the problems of a wholly internal penile implant. The videotaped operation showed both rigidity for intercourse and operability of the valve to inflate and deflate the device through the skin. The use of materials previously shown to work in prosthetic implants over a reasonable period of time also showed the durability of the invention for its intended purpose. In sum, Dr. Scott showed sufficient testing to establish a reasonable expectation that his invention would work under normal conditions for its intended purpose, beyond a probability of failure.

The Board erred by setting the reduction to practice standard too high. The Board erroneously suggested that a showing of reduction to practice requires human testing in actual use circumstances for a period of time. *See Engelhardt v. Judd*, 369 F.2d 408, 410–11, 151 USPQ 732, 734 (CCPA 1966) (human testing of antihistamine and antiserotonin unnecessary in light of tests on laboratory animals). Reduction to practice, however, does not require actual use, but only a reasonable showing that the invention will work to overcome the problem it addresses. The videotape showed the rigidity and manipulability of the valve through the skin necessary for actual use. Experts testified to the invention's suitability for actual use. In the context of this art and this problem, Dr. Scott made that reasonable showing.

The Board rejected these proofs because the device was not actually used during intercourse. In this instance of a solution to a relatively simple problem, the Board required more testing than necessary to show that the device would work for its intended purpose. Even accepting the Board's conclusion that the intended purpose is to facilitate normal sexual intercourse, prior art prosthetic devices had fully tested the workability of most features of Dr. Scott's invention. Dr. Scott used the same tested and workable materials and designs of prior art implants. Only the hydraulics of a fully self-contained internal prosthesis remained to be tested for workability. Dr. Scott adequately showed the workability of these features.

Testing for the full safety and effectiveness of a prosthetic device is more properly left to the Food and Drug Administration (FDA). Title 35 does not demand that such human testing occur within the confines of Patent and Trademark Office (PTO) proceedings. *Cf. In re Sichert*, 566 F.2d 1154, 1160, 196 USPQ 209, 214 (CCPA 1977) (rejecting lack

of safety challenge to utility of claimed drug); *In re Anthony*, 414 F.2d 1383, 1395, 162 USPQ 594, 604 (CCPA 1969) ("Congress has given the responsibility to the FDA, not to the [PTO], to determine . . . whether drugs are sufficiently safe . . . .") (citation omitted); *In re Watson*, 517 F.2d 465, 476, 186 USPQ 11, 19 (CCPA 1975) (same).

The Board's holding that Dr. Scott did not reduce his invention to practice before the May 15, 1980 filing date of Dr. Finney is reversed. Dr. Finney asserted that Dr. Scott abandoned, suppressed, or concealed the invention embodied by the count within the meaning of 35 U.S.C. § 102(g) (1988). The Board did not reach this issue in light of its holding that no reduction to practice occurred. Because the Board has not considered this issue, this court remands for a determination of whether Dr. Scott abandoned, suppressed, or concealed the invention within the meaning of 35 U.S.C. § 102(g).

COSTS

Each party to bear its own costs.

REVERSED AND REMANDED.

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